

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No. 21-1015 (GBW)

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

REDACTED - PUBLIC VERSION

**DEFENDANTS' REPLY LETTER BRIEF TO
THE HONORABLE GREGORY B. WILLIAMS IN SUPPORT OF
THEIR MOTION TO STRIKE DR. MATTHEW WOOD'S EXPERT REPORTS**

Dear Judge Williams:

As addressed in Sarepta's prior briefing (D.I. 298 at 2-3), the prejudice resulting from Dr. Wood's "switching sides" and the risk of disclosure to NS of Sarepta's confidential information previously provided to Dr. Wood justifies striking his expert reports. In addition, in August, Dr. Wood, in trying to avoid being disqualified from being adverse to Sarepta based on [REDACTED]

[REDACTED]

However, in his expert reports, Dr. Wood provided opinions directly addressing NS's defense that the Wilton Patents are invalid under 35 U.S.C. § 112, including what a person of ordinary skill in the art ("POSA") would have understood the Wilton Patent inventors to have invented:

A POSA reviewing the UWA Specification in June 2005 would not have understood the inventors to have invented the structural features recited in the claims that were submitted in 2017 and which Dr. Dowdy claims collectively confer exon 53 skipping activity."

Wood Reply Report, ¶ 40 (D.I. 385-1, Ex. 3 (emphasis added).)

When I use the term "invented" I am referring to what a POSA would have understood the inventors possessed, recognized, appreciated, conceived, or had a definite and permanent idea of as of the June 28, 2005 filing date of the [Wilton] Patents.

Id. at ¶ 17 n.3 (emphasis added).

In its opposition to this motion, NS confirms that Dr. Wood's opinions are directed to what a POSA would have understood the inventors had invented based on the specifications:

In expert discovery, Dr. Wood offered opinions . . . [REDACTED]

(D.I. 387 at 2 (emphasis added).)

Although the word "invalid" does not appear in Dr. Wood's reports, his opinions employ the language used in cases holding claims invalid under § 112. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) ("the [written] description must 'clearly allow *persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.*'" (emphasis added), quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63

The Honorable Gregory B. Williams

December 11, 2023

Page 2

(Fed.Cir.1991)); *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332, 1341 (Fed. Cir. 2013) (“Section 112, paragraph one of Title 35 requires a patentee to provide a written description that allows **a person of skill in the art to recognize that the patentee invented what is claimed.**”) (emphasis added); *accord ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368 (Fed. Cir. 2009) (holding claims invalid under § 112 where “a person of skill in the art would not understand the inventor . . . to have invented” the claimed invention). Findings regarding what a POSA would have recognized or understood the inventors to have invented are thus pertinent to evaluating written description.

Indeed, Judge Andrews recently held patent claims invalid for lack of written description based on a POSA’s understanding of what the inventor had invented. *See Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, No 19-1727-RGA, 2023 WL 6295496, at *6, *12, *21 (D. Del. Sep. 27, 2023) (finding “a POSA reading the specification would not understand the patentee to have invented” the claimed formulation).

Dr. Wood’s opinions “as to **what a person of ordinary skill in the art would understand the inventors had invented**” (D.I. 387) directly “concern[] the . . . validity” of the Wilton Patents, [REDACTED] That alone is grounds for striking his reports.

Finally, NS’s assertion that it would be prejudiced by the exclusion of Dr. Wood (D.I. 387 at 3) rings hollow because another of its technical experts, Dr. Hastings, [REDACTED] . *See* Hastings Opening Report at ¶¶ 1, 51 (Ex. 1); Hastings Reply Report at ¶ 18 (Ex. 2). In any event, NS decided to proceed with Dr. Wood with its eyes wide open. Well before NS submitted Dr. Wood’s expert reports, Sarepta had clearly and repeatedly voiced its objection to NS’s use of Dr. Wood. D.I. 300-1; *see also* D.I. 298, 307. Thus, any prejudice to NS is self-inflicted.

Sarepta respectfully requests that the Court strike Dr. Wood’s expert reports and disqualify him from serving as an expert for NS.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac
Attachments

cc: Clerk of the Court (via hand delivery; w/attachments)
All Counsel of Record (via electronic mail; w/attachments)